

REMARKS/ARGUMENTS

The non-Final Office Action mailed March 9, 2007 has been received and reviewed. Prior to the present communication, claims 1-27 were pending in the subject application. All claims stand rejected. Claims 1, 7, 11, 17 and 21-27 have been amended as hereinabove set forth and claims 6 and 16 have been cancelled. Accordingly, claims 1-5, 7-15 and 17-27 remain pending. Reconsideration of the present application in view of the above amendments and the following remarks is respectfully requested.

Rejections based on 35 U.S.C. § 101

Claims 11-20 have been rejected under 35 U.S.C. § 101 as being directed towards non-statutory subject matter. Claim 11 has been amended herein to recite “storing the aggregation of the patient supply consumption data”. It is respectfully submitted that claim 11, as currently amended, is directed towards statutory subject matter. Accordingly the rejection of this claim is believed to have been overcome. Each of claims 12-20 depends, either directly or indirectly, from independent claim 11. Accordingly, each of these claims is believed to be directed towards statutory subject matter for at least the above-cited reasons. Accordingly, withdrawal of the 35 U.S.C. § 101 rejection of claims 11-20 is respectfully requested.

Rejections based on 35 U.S.C. § 102

A. Applicable Authority

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdeggal Brothers v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the . . .

claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 2 USPQ 2d 1913, 1920 (Fed. Cir. 1989). *See also*, MPEP § 2131.

B. Rejections based on U.S. Patent 5,682,728 to DeBusk.

Claims 1–4, 6–14, 16–22 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,682,728 to DeBusk et al. (hereinafter the “DeBusk reference”). As the DeBusk reference fails to describe, either expressly or inherently, each and every element of the rejected claims, Applicants respectfully traverse this rejection, as hereinafter set forth.

Independent claim 1, as amended herein, recites a system for managing patient supply data. The system includes an input interface to receive patient supply data captured from at least one clinically related site, a data store and a report engine. The data store stores the patient supply data and the report engine communicates with the data store to generate consumption reports based upon at least individual patient information, the consumption reports comprising a bill of resources used and/or consumed during a clinical event.

The DeBusk reference, on the other hand, describes the management of consumable medical supplies by creating bills of material associated with care events within a clinical pathway. *See* DeBusk reference at col. 2 lines 29–37. A bill of materials representing those medical supplies that have been identified as “to be used” for a given care event is generated and supplies are aggregated into supply bundles at a plurality of locations and delivered to the end-user of the aggregated supplies. *See id.* at col. 2 line 50–col. 3, line 2; col. 3, line 34. The DeBusk reference also discloses anticipating supply usage based upon historical records relating to the frequency of occurrence of given care events at a particular facility and/or aggregated facility usage of common medical supplies over time. *See id.* at col. 2 line 59–col. 6,

line 13. Further, the DeBusk reference describes generating various reports using the bill of materials. *See id.* at col. 2 lines 41-49.

However, the DeBusk reference fails to describe, either expressly or inherently, generating consumption reports based upon at least individual patient information, the consumption reports comprising a bill of resources used and/or consumed during a clinical event. The DeBusk reference does not disclose recording the supplies that are actually used and/or consumed during clinical events but rather describes the management and procurement of supply bundles containing medical supplies “intended for use” in a future care event. *See* DeBusk reference at col. 5, lines 22-45. As will be appreciated by one of ordinary skill in the art, upon occurrence of the future care event, some of the items included in the supply bundle may not be used all. As such, the supplies “intended for use” and the supplies actually used or consumed during a clinical event cannot be equated.

It is stated in the Office Action (with reference to dependent claim 6), that the DeBusk reference “teaches [a] system wherein the consumption reports comprise a bill of resources consumed during the course of clinical treatment (see column 4, lines 30-50).” *Office Action* at page 3, ¶ 9. It is respectfully submitted, however, that the referenced section of the DeBusk reference merely describes a bill of materials representing items “intended for use” in a future care event which does not equate to supplies actually used and/or consumed.

As the DeBusk reference fails to describe, either expressly or inherently, each and every element recited in independent claim 1, as amended herein, it is respectfully submitted that the DeBusk reference does not anticipate this claim. Each of claims 2-5 and 7-10 depends, either directly or indirectly, from independent claim 1. Accordingly, it is respectfully submitted that these claims are not anticipated by the DeBusk reference for at least the above-cited reasons.

Accordingly, withdrawal of the 35 U.S.C. § 102(b) rejection of claims 1–5 and 7–10 is respectfully requested. Each of claims 1–5 and 7–10 is believed to be in condition for allowance and such favorable action is respectfully requested.

Claim 6 has been cancelled by way of the present communication and, accordingly, the rejection of this claim has been rendered moot.

Independent claim 11, as amended herein, recites a method for managing patient supply data. The method includes receiving patient supply data captured from at least one clinically related site, storing the patient supply data to a data store, generating consumption reports based upon at least individual patient information, and storing the aggregated patient supply data. The consumption reports comprise a bill of resources used and/or consumed during a clinical event.

As stated herein above with reference to claim 1, the DeBusk reference fails to describe, either expressly or inherently, consumption reports comprising a bill of resources used and/or consumed during a clinical event. Rather, the DeBusk reference describes the management and procurement of supply bundles containing medical supplies “intended for use” in a future care event. *See*, DeBusk reference at col. 5, lines 22–45. As will be appreciated by one of ordinary skill in the art, upon occurrence of the future care event, some of the items included in the supply bundle may not be used all. As such, the supplies “intended for use” and the supplies actually used or consumed during an event cannot be equated.

It is stated in the Office Action (with reference to dependent claim 16), that the DeBusk reference “teaches [a] method wherein the consumption reports comprise a bill of resources consumed during the course of clinical treatment (see column 4, lines 30–50).” *Office Action* at page 5, ¶ 18. It is respectfully submitted, however, that the referenced section of the

DeBusk reference merely describes a bill of materials representing items “intended for use” in a future care event which does not equate to supplies actually used and/or consumed.

As the DeBusk reference fails to describe, either expressly or inherently, each and every element recited in independent claim 11, as amended herein, it is respectfully submitted that the DeBusk reference does not anticipate this claim. Each of claims 12–15 and 17–20 depends, either directly or indirectly, from independent claim 11. Accordingly, it is respectfully submitted that these claims are not anticipated by the DeBusk reference for at least the above-cited reasons. Accordingly, withdrawal of the 35 U.S.C. § 102(b) rejection of claims 11–15 and 17–20 is respectfully requested. Each of claims 11–15 and 17–20 is believed to be in condition for allowance and such favorable action is respectfully requested.

Claim 16 has been cancelled by way of the present communication and, accordingly, the rejection of this claim has been rendered moot.

Claim 21, as amended herein, recites one or more computer-readable media having computer-executable instructions embodied thereon for performing a method for generating a patient supply record. The method includes capturing patient supply data from a plurality of departments during a patient encounter, associating the patient supply data with at least corresponding individual patient records, and storing the patient supply data to a data store. The patient supply data comprises items used and/or consumed during a clinical event.

It is respectfully submitted that the DeBusk reference fails to describe, either expressly or inherently, patient supply data comprising items used and/or consumed during a clinical event. Rather, the DeBusk reference describes the management and procurement of supply bundles containing medical supplies “intended for use” in a future care event. *See*, DeBusk reference at col. 5, lines 22–45. As will be appreciated by one of ordinary skill in the

art, upon occurrence of the future care event, some of the items included in the supply bundle may not be used all. As such, the supplies “intended for use” and the supplies actually used or consumed during an event cannot be equated.

As the DeBusk reference fails to describe, either expressly or inherently, each and every element recited in independent claim 21, as amended herein, it is respectfully submitted that the DeBusk reference does not anticipate this claim. Each of claims 22–27 depends, either directly or indirectly, from independent claim 21. Accordingly, it is respectfully submitted that these claims are not anticipated by the DeBusk reference for at least the above-cited reasons. Accordingly, withdrawal of the 35 U.S.C. § 102(b) rejection of claims 21–27 is respectfully requested. Each of claims 21–27 is believed to be in condition for allowance and such favorable action is respectfully requested.

Rejections based on 35 U.S.C. § 103

A. Applicable Authority

The basic requirements of a *prima facie* case of obviousness are summarized in MPEP § 2143 through § 2143.04. In order “[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success [in combining the references]. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)”. See MPEP § 2143. Recently, the Supreme Court elaborated,

at pages 13-14 of the *KSR* opinion, that “it will be necessary for [the Office] to look at interrelated teachings of multiple [prior art references]; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by [one of] ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the [patent application].” *KSR v. Teleflex*, No. 04-1350, 550 U.S. ____ (2007).

Further, in establishing a *prima facie* case of obviousness, the initial burden is placed on the Examiner. “To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 USPQ 972, 972, (Bd. Pat App. & Inter. 1985).” *Id.* See also MPEP § 706.02(j) and § 2142.

B. Rejections based on the DeBusk reference in view of U.S. Patent No. 6,151,582 to Huang et al.

Claims 5 and 15 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the DeBusk reference in view of U.S. Patent No. 6,151,582 to Huang et al (hereinafter the “Huang reference”). As the DeBusk reference and the Huang reference, whether taken alone or in combination, fail to teach or suggest all of the limitations of the rejected claims, Applicants respectfully traverse this rejection, as hereinafter set forth.

Claim 5 depends directly from independent claim 1. As previously set forth, the DeBusk reference, fails to describe each and every element of independent claim 1, as amended herein. Specifically, the DeBusk reference fails to describe generating consumption reports

based upon at least individual patient information, the consumption reports comprising a bill of resources used and/or consumed during a clinical event.

It is respectfully submitted that the Huang reference does not cure this deficiency or the DeBusk reference, nor is it relied upon for such teaching. Rather, the Huang reference describes a supply-chain-optimization system that is used in manufacturing and commercial environments. The Huang reference is not related to patients and/or patient supply data of any kind. *See generally*, Huang reference.

Accordingly, it is respectfully submitted that the DeBusk reference, the Huang reference, and/or any combination thereof, fails to teach or suggest all of the limitations of independent claim 1, as amended herein. As such, the cited references also fail to teach or suggest all of the limitations of dependent claim 5. Accordingly, withdrawal of the 35 U.S.C. § 103(a) rejection of dependent claim 5 is respectfully requested. Claim 5 is believed to be in condition for allowance and such favorable action is respectfully requested.

Claim 15 depends directly from independent claim 11. As previously set forth, the DeBusk reference, fails to describe each and every element of independent claim 11, as amended herein. Specifically, the DeBusk reference fails to describe generating consumption reports comprising a bill of resources used and/or consumed during a clinical event.

It is respectfully submitted that the Huang reference does not cure this deficiency in the DeBusk reference, nor is it relied upon for such teaching. Rather, the Huang reference describes a supply-chain-optimization system that is used in manufacturing and commercial environments. The Huang reference is not related to patients and/or patient supply data of any kind. *See generally*, Huang reference.

Accordingly, it is respectfully submitted that the DeBusk reference, the Huang reference, and/or any combination thereof, fails to teach or suggest all of the limitations of independent claim 11, as amended herein. As such, the cited references also fail to teach or suggest all of the limitations of dependent claim 15. Accordingly, withdrawal of the 35 U.S.C. § 103(a) rejection of dependent claim 15 is respectfully requested. Claim 15 is believed to be in condition for allowance and such favorable action is respectfully requested.

C. Rejections based on the DeBusk reference in view of U.S. Publication No. 2002/0188469 to Shalmi et al.

Claim 23 has been rejected under 35 U.S.C. § 103(a) as being anticipated by the DeBusk reference in view of U.S. Publication No. 2002/0188469 to Shalmi et al (hereinafter the "Shalmi reference"). As the DeBusk reference and the Shalmi reference, whether taken alone or in combination, fail to teach or suggest all of the limitations of the rejected claims, Applicants respectfully traverse this rejection, as hereinafter set forth.

Claim 23 depends directly from independent claim 21. As previously set forth, the DeBusk reference, fails to describe each and every element of independent claim 21, as amended herein. Specifically, the DeBusk reference fails to describe patient supply data comprising items used and/or consumed during a clinical event.

It is respectfully submitted that the Shalmi reference does not cure this deficiency of the DeBusk reference, nor is it relied upon for such teaching. Rather, the Shalmi reference describes a pharmaceutical distribution and sales method wherein quantities of pharmaceuticals are contracted based upon potential patient use. *See* Shalmi reference at Abstract. The Shalmi reference does not describe patient supply data that was used and/or consumed during a clinical event.

Accordingly, it is respectfully submitted that the DeBusk reference, the Shalmi reference, and/or any combination thereof, fails to teach or suggest all of the limitations of independent claim 21, as amended herein. As such, the cited references also fail to teach or suggest all of the limitations of dependent claim 23. Accordingly, withdrawal of the 35 U.S.C. § 103(a) rejection of dependent claim 23 is respectfully requested. Claim 23 is believed to be in condition for allowance and such favorable action is respectfully requested.

CONCLUSION

For at least the reasons stated above, claims 1–5, 7–15, and 17–27 are believed to be in condition for allowance and such favorable action is respectfully requested. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned by telephone prior to issuing a subsequent action.

The fee for a one-month extension of time is submitted herewith. It is believed that no additional fee is due in conjunction with the present communication. However, if this belief is in error, the Commissioner is hereby authorized to charge any additional amount required to Deposit Account No. 19-2112, referencing attorney docket number CRNI.111421.

Respectfully submitted,

/Tawni L. Wilhelm/

Tawni L. Wilhelm
Reg. No. 47,456

DPD/TLW/JOH
SHOOK, HARDY & BACON L.L.P.
2555 Grand Blvd.
Kansas City, MO 64108-2613
816-474-6550